REMARKS

Favorable reconsideration and allowance of the present application are respectfully requested in view of the foregoing amendments and the following remarks.

Currently, claims 113-129 are pending in the present application, including independent claim 113. Independent claim 113, for instance, is directed to a diagnostic device having a housing that defines i) an opening for receiving a sample, ii) a first chamber into which the sample may be directed, iii) a first channel positioned to provide unreacted sample from the opening to the first chamber, and iv) a second channel positioned to remove unreacted sample from the first chamber. A test strip is removably attached to the housing that defines a test surface in fluid communication with the first chamber so that the sample may be reacted. A second chamber is positioned for receipt of unreacted sample from the first chamber. The second chamber is in fluid communication with the second channel. The device also includes means for inducing a negative pressure differential on the sample to direct the sample through the first channel, into the chamber, to the test surface, and to thereafter remove an unreacted portion of the sample from the test surface, through the second channel, and into the second chamber.

In the Office Action, independent claim 113 was initially rejected under *35 U.S.C. § 112*, first paragraph, for failing to satisfy the written description requirement. Specifically, it was stated that the "second channel" is not supported in the specification or drawings. Fig. 3, however, clearly illustrates the second channel 26. Applicants have thus amended the specification to simply reflect the identification of this channel as the "second channel." The Office Action also objected to the nomenclature "first" and

"second" in independent claim 113 as being vague and indefinite under 35 U.S.C. § 112, second paragraph. For sake of clarity, Applicants have thus been amended the specification to identify embodiments in which "first" and "second" channels and "first" and "second" chambers may be employed. No new matter is being added by these amendments. For at least the reasons noted, Applicants respectfully submit that independent claim 113 fully satisfies all of the requirements of *§ 112.*

The Office Action also rejected independent claim 113 under *35 U.S.C. § 103(a)* as being obvious over U.S. Patent No. 5,677,133 to Oberhardt. Oberhardt is directed to a method for performing an affinity assay comprising: (1) contacting a sample to be assayed for the presence of an analyte with a dry reagent containing the analyte bound to a reaction cascade initiator, an antibody reactive with the analyte, and magnetic particles, to form an assay mixture in a reaction chamber; (2) incubating the assay mixture; (3) applying an oscillating or moving static magnetic field to the assay mixture; (4) activating the reaction cascade initiator to initiate a reaction cascade; (5) monitoring the response of the magnetic particles to the oscillating or rotating magnetic field to provide a time varying signal; and (6) determining the analyte concentration of the sample by analysis of the time varying signal. (Col. 4, lines 48-64). Oberhardt describes carrying out its affinity assay method using a reaction slide, such as shown in Figures 1-4.

However, Oberhardt lacks certain limitations of independent claim 113. Oberhardt indicates the use of a vacuum to cause movement of a sample from a sample well to a reaction chamber. To use such vacuum, Oberhardt uses a liquid impermeable membrane to pull the liquid sample to the reaction chamber without

removing the liquid sample from the reaction chamber. More specifically, no additional channel or additional chamber is provided for receipt of the liquid sample from the reaction chamber because the liquid sample is not removed from Oberhardt's reaction chamber. In fact, such liquid could not be removed from Oberhardt's reaction chamber with a vacuum because Oberhardt specifically indicates the placement of a liquid impermeable membrane on vent 76 of the reaction chamber in order to draw a vacuum without removing the liquid sample.

Thus, unlike the limitations of independent claim 113, Oberhardt does not indicate "a second channel positioned to remove unreacted sample from the first chamber" because Oberhardt does not remove liquid sample from the reaction chamber. In addition, unlike the limitations of independent claim 113, Oberhardt does not indicate "a second chamber positioned for receipt of unreacted sample from the first chamber" because Oberhardt does not remove liquid sample from its reaction chamber. Furthermore, unlike the limitations of independent claim 113, Oberhardt does not have "means for inducing a negative pressure differential on the sample to direct the sample through the first channel, into the chamber, to the test surface, and to thereafter remove an unreacted portion of the sample from the test surface and into the second chamber" because Oberhardt does not remove any sample from its reaction chamber and does not have a second chamber.

Moreover, independent claim 113 also requires a test strip that *defines a test surface* and that is *removably attached* to a housing and is in fluid communication with the first chamber by a second opening formed in the first chamber. In this manner, the test strip may be easily removed for viewing or placement in an analyzer. In contrast,

Oberhardt's reaction plate 20 itself defines or forms part of the reaction chamber 62 (Fig. 4A). Unlike claim 113, reaction plate 20 is not removably attached to a housing. Finally, Oberhardt's reaction plate 20 is not attached a housing that comprises a second opening for reacting the sample.

In the recent Office Action, the Examiner acknowledged the failure of Oberhardt to disclose the multiple limitations referenced above. However, the Office Action indicated that "Oberhardt discloses that his invention may be modified in light of his disclosure" and that it would have been obvious [to] a person of ordinary skill in the art to incorporate additional channels and openings . . . because it would be desirable and more efficient to have a plurality of channels and openings to allow more than one sample to be analyzed simultaneously, or alternatively, it would allow one sample to under multiple analyses simultaneously." Oberhardt, however, lacks any teaching whatsoever, whether express or implied, for simply adding channels to analyze multiple analytes. The mere fact that the prior art *may* be modified in the manner suggested does not make the modification obvious.

In any event, a prima facie case of obviousness is made only when the claimed invention *taken as a whole* is obvious based a modification of a reference. In this case, even if one were motivated to employ multiple "channels" and "chambers" as suggested in the Office Action, no reasonable justification exists for doing so in the specific manner claimed. By way of example, Applicants' specification and Figures illustrate embodiments of a diagnostic device in which a syringe 50 is used to clear an unreacted portion of the sample from test surface 42 by directing the unreacted portion of the sample past through a channel and to a chamber 56 for containing the unreacted

portion of the sample. In Oberhardt, however, the reaction slide is set up so that any sample to be analyzed merely travels from sample well 64 to the reaction chamber (e.g., reaction chamber 62 in Figures 1-4 or reaction chambers 109, 110, 111, and 112 in Figure 11). When the sample in Oberhardt reaches the reaction chamber, the entire sample is contacted with the dry reagent to form an assay mixture, and the other steps in the assay method (e.g., incubating the assay mixture, applying a magnetic field to the assay mixture, activating the reaction cascade initiator, monitoring a response using optical means, and ultimately determining the concentration of an analyte) all take place while the assay mixture remains in the reaction chamber. (Col. 5, lines 9-11 and 48-63). Nothing in Oberhardt teaches or in any way suggests equipping a diagnostic device with the particular arrangement of channels and chambers claimed.

Plainly, the only incentive or motivation for so modifying Oberhardt in the manner suggested in the Office Action results from using Applicants' disclosure as a blueprint to reconstruct the claimed invention out of isolated teachings in the prior art, which is improper under *35 U.S.C. § 103*.

Thus, for at least the reasons set forth above, Applicants respectfully submit that the present claims are not anticipated by Oberhardt. Furthermore, Applicant respectfully submits that some or all of the dependent claims also contain additional limitations not indicated by Oberhardt. By way of example only, claim 117 requires that the means for inducing a negative pressure is a syringe, and claim 118 requires the syringe to have indicators correlated with the rest of the device so as to mark the position of the sample within the device.

It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Snay is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,

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